REMARKS

Claims 1-6, 8-12, 17-19, and 46-47 are pending in the application and all claims are rejected. Applicant respectfully requests reconsideration of the rejections in view of the remarks that follow.

Claim 1 has been amended to include the limitations of claim 15. Claims 15, 48, and 49 have been canceled. No new matter has been added.

The Invention

The present invention is directed to a device for brain cooling to reduce brain damage caused by a decrease in blood flow. The human brain is highly susceptible to injury following the reduction of blood flow which often accompanies injuries such as, for example, ischemic stroke, cardiac or respiratory arrest, or severe head trauma or intracerebral hemorrhage with elevated intracranial pressure. By cooling the brain, the present invention slows metabolic activity and the demand for blood carried nutrients, and thereby reduces the effects of diminished blood flow.

Unlike other attempts at brain cooling, which have focused on cooling arterial blood or other non-brain portions of a patient's body, the present invention directly contacts and cools brain tissue. Applicant has found that direct cooling provides highly specific cooling for treating and protecting the brain, while minimize damage to other areas of the body.

Applicant's invention facilitates such improved brain cooling in a device designed to safely treat brain tissue. A temperature measuring element positioned on the device to measure the temperature of the target tissue allows a user to carefully monitor cooling at the tissue surface to monitor the progress of cooling and thus achieve optimal results. Additionally, a pressure measurement element, with a first end positioned in proximity to the implantable member, is effective to measure the pressure at which the implantable member is applied to the target tissue. The pressure measurement element is an important feature of the device because it enables the claimed device to be placed in direct contact with delicate brain tissue to enable more effective cooling and treatment, while avoiding damage to the brain tissue.

The Cited Prior Art

Unlike the present invention, the cited prior art is not concerned with the delicate nature of brain tissue and/or minimizing damage to the brain as a result of trauma. Instead, the primary references cited in the pending Office Action, (Lafontaine, Wittenberger et al., and Milder), are directed to ablation devices used to treat cardiac or arterial tissue. These devices are designed to burn away tissue to treat cardiac arrhythmias or restenosis.

In addition, the devices disclosed in these references are catheters used to destroy specific tissue regions during minimally invasive procedures. There is no suggestion or disclosure that they would be effective to cool brain tissue. Instead these devices are designed to utilize cooling to treat the vascular system. They are not useful to treat brain ischemia because the brain blood flow is so high that intravascular cooling of brain inherently involves total body cooling with its accompanying health risks of infection, hemodynamic changes, and cardiac arrhythmia. The vascular technique disclosed by these references is also ineffective because they target brain tissue with very low blood flow for cooling.

No cited reference discloses an implantable, direct brain-contacting cooling element that is effective to cool brain tissue. Moreover, the cited art fails to disclose such a system with the added feature of a pressure sensing system that detects the pressure at which the implantable element is applied to delicate brain tissue. This combination provides effective, direct cooling while ensuring that the cooling element does not contact the brain with such force as to cause additional damage.

Moreover, a person of ordinary skill in the art would have no motivation to adapt these devices for treating brain injuries. Nowhere in any of these references is there a suggestion that they could be used for such a treatment, and in fact, they are designed for treatments incompatible with brain cooling.

Claim Rejection – 35 U.S.C. § 102

Claims 1-5, 7-12, 19, 46, and 48-49 are rejected pursuant to 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5,868,735 to Lafontaine; by U.S. Patent No. 5,281,215 to Milder; and/or Patent No. 6,106,518 to Wittenberger et al. ("Wittenberger"). In particular, it is alleged that the cited references provide a device for thermally treating tissue which includes an

implantable member having an outer surface for contacting target tissue, a fluid tight lumen configured to receive a thermally transmissive fluid, and temperature sensors. In addition, the Examiner alleges that these devices could be used to cool brain tissue.

Applicant respectfully traverses these rejections.

Amended claim 1 requires an apparatus for thermally affecting brain tissue including an implantable member having an outer surface configurable to contact target brain tissue and at least one fluid-tight lumen defined by the implantable member, the fluid-tight lumen being in thermal communication with the outer surface of the implantable member and being configured to receive a thermally transmissive cooling fluid to thereby impart a thermal change to the outer surface of the implantable member. In addition, the apparatus has a first temperature sensing element that is effective to measure the temperature of the target tissue. A pressure measurement element is also included having a first end positioned in proximity to the implantable member and effective to measure the pressure at which the implantable member is applied to the target tissue.

Unlike the minimally invasive angioplasty and ablation devices described in the cited references, the apparatus of the present invention is adapted for brain cooling by direct contact with brain tissue. The implantable member of the present invention allows the device to be positioned directly in contact with brain tissue, while the temperature sensor and the pressure sensor respectively monitor the tissue temperature and the pressure exerted on the brain to determine the progress of the treatment and to help to assure the safety of the brain tissue.

The Lafontaine, Milder, and Wittenberger references each fail to disclose any apparatus adapted to cooling brain tissue. Moreover, each cited reference lacks the claimed temperature and pressure sensors for protecting and monitoring sensitive brain tissue as are required by independent claim 1. In particular, none of the references has a pressure measurement element with a first end positioned in proximity to the implantable member and effective to measure the pressure at which the implantable member is applied to the target tissue. Thus, none of these references can anticipate claim 1 and the rejection under 35 U.S.C. §102 cannot stand.

Claims Rejections – 35 U.S.C. § 103

Claims 12 and 49 are rejected pursuant to 35 U.S.C. §103(a) as obvious over Lafontaine in view of Milder. In particular, the Examiner states that Lafontaine fails to disclose placing the second temperature sensor such that it can sense the temperature of the cooling fluid being delivered to the implantable device. Milder is cited to teach placing a temperature sensor within a tube for sensing the temperature of a cooling liquid.

Applicant respectfully traverses this rejection.

Neither Lafontaine nor Milder discloses a device adapted for brain cooling, as required by claims 12 and 49. Instead, these references teach cryogenic catheters for minimally invasive cryogenic therapies for coronary ablation. These references also fail to provide any suggestion or motivation for adapting their devices for brain cooling.

The Lafontaine and Milder also fail to disclose or suggest a pressure measuring element having a first end positioned in proximity to the implantable member and effective to measure the pressure at which the implantable member is applied to the target tissue. As noted above, this is an important element of the brain cooling device of the present invention because it ensures effective, direct cooling while at the same time ensuring that brain tissue is not further damaged.

Claims 15, 17, and 18 are rejected pursuant 35 U.S.C. §103(a) as being obvious over Lafontaine in view of US. Patent No. 5,891,134 to Goble et al. ("Goble"). The Examiner admits Lafontaine fails to disclose a pressure sensor, but cites Goble as disclosing a thermally transmissive balloon apparatus for applying pressure and thermal energy to tissue and having a pressure sensor for regulating pressure in the balloon.

Applicant respectfully traverses the rejection.

As the Examiner recognizes, Goble discloses an expandable balloon, a device quite dissimilar to the claimed invention. This balloon is designed for expansion within bodily cavities so that the walls of the cavity can be treated with *heat*. The pressure sensor is used with the control system to regulate the fluid pressure *within the balloon*. As Goble explains at column 4, lines 50 – 64, the pressure within the balloon is significant because different pressures

must be achieved to treat different conditions. Unlike Goble, the pressure sensor of the present invention has a pressure measurement element effective to measure the pressure at which the implantable member is applied to the target brain tissue. Thus, the claimed pressure measurement element measures pressure between the surface of the device and the brain tissue as opposed to pressure within a fluid filled balloon. This is an important distinction because Gobles device does not have the ability to detect the pressure at which it contacts any tissue. It instead only measures fluid pressure within the balloon. This teaching related to *fluid* pressure monitoring, in connection with a device that ablatively *heats* endometrial tissue, simply provides no motivation to provide a device that cools brain tissue and monitors the pressure at which the cooling device contacts brain tissue.

Claim 1 also requires that the pressure measuring element be positioned in proximity to the implantable member that contacts brain tissue. The position of the pressure measuring element allows for monitoring of the brain contact pressure to avoid damage to the brain. Conversely, Goble describes a pressure sensor (illustrated as 58 in FIG. 1) positioned remotely from the inflatable balloon for measuring only fluid pressure within flexible tubing 56. These teachings have no relevance to the claimed invention and certainly provide no motivation to modify an equally unrelated device, such as described in Lafontaine, to mimic the claimed invention. Any attempt to combine these references to reject claims 15, 17, and 18 necessarily relies on hindsight and is not permissible.

In view of the forgoing remarks, Applicant submits that all pending claims are in condition for allowance and Applicant respectfully requests allowance thereof. The Examiner is urged to

telephone the undersigned attorney for Applicants in the event that such communication is deemed to expedite allowance of this application.

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Respectfully submitted,

By _____

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